Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume VIII Issue 2 February 2003

Conference Highlights: HIPAA Update

by Leonard Kargacin

Marguerite Busch, Compliance Officer for Pathology Associates Medical Laboratories in Spokane, presented an update on HIPAA at the 9th Annual Clinical Laboratory Conference entitled "HIPAA Compliance Update: What's New, What's Different, What's in Transition?" The following is a synopsis of this presentation.

The Health Insurance Portability and Accountability Act (HIPAA) was passed in 1996. This law has been in effect since 1996 and the absence of published final rules does not mean that the law is not currently in effect and enforceable.

Key Terms:

- Covered entity: a provider, payer, or clearinghouse
- PHI: protected health information
- Business Associate: a 3rd party who performs a non-clinical task on behalf of a covered entity that includes access to PHI
- Use: utilization of PHI internal to the covered entity
- Disclosure: sharing of PHI external to the covered entity
- TPO (Treatment, Payment, Health Care Operations): sharing of PHI for TPO is allowed under HIPAA
- Treatment: either direct or indirect patient care interaction
- Payment: auditing, remittance processing, and documentation for claims payment
- Health Care Operations: includes quality improvement and quality assurance activities, peer review, medical education or anything that helps maintain the quality of care
- Consent: permission to use or disclose PHI for TPO
- Authorization: permission to use or disclose PHI for any purpose other than TPO (always specific - no such thing as a blanket authorization)
- Minimum Necessary: availability/use of the minimum PHI necessary for the purpose/task at hand
- Need to Know: policy as to what information is appropriate for a given staff member/department to use or disclose in line with their assigned responsibilities.

What's New:

The deadline to file an extension (for a compliance date of October 16, 2003) for the electronic data interchange (EDI) portion of HIPAA was October 15, 2002. If the covered entity did not apply for the extension by October 15, 2002, the transaction and code set rules apply **now**.

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Inside This Issue

Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

- Anemia
- ANA
- Bioterrorism Event Mgmt
- Bleeding Disorders
- Chlamydia
- Diabetes
- Group A Strep Pharyngitis
- Hepatitis
- HIV
- Intestinal Parasites
- Lipid Screening
- Point-of-Care Testing
- PSA
- Renal Disease
- STD
- Thyroid
- Tuberculosis
- Urinalysis
- Wellness

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What's Different:

- The Modified Privacy Rules were finalized on August 14, 2002. The implementation deadline is April 14, 2003.
- Revised implementation dates for the Business Associate Agreements: For contracts that were in existence before October 15, 2002, and are not due to be renewed or modified prior to April 2003, you have until April 2004 to include the new language. For new contracts, you need to include the new language in the agreement now.

What's in Transition:

The security rules have still not been published. It is important that facilities not assume that providing security for PHI can wait until the rules are finalized.

Modifications to the Privacy Standards:

- Prior written consent for use and disclosure of PHI was eliminated for routine health care delivery. However, if you do get consent from patients, you must follow ALL of the rules where patients can revoke their consent for you to use that information.
- Direct treatment providers are required to make a "good faith" effort to inform patients of their privacy rights. Laboratories almost always are considered indirect treatment providers. A laboratory may be a direct treatment provider if it accepts direct access testing from patients. **NOTE:** Laboratory testing performed in a POL on its own patients is considered direct treatment, but the facility should have already provided the necessary privacy information to the patient.
- Parental access to their child's medical records defers to state and other laws.
- Authorization of PHI disclosure for research purposes is simplified.

Key Issues/Challenges:

- Designation of a "Privacy Officer" - There should also be a security officer, but should probably not be the same person as the privacy officer.
- Applying the Minimum Necessary/Need to Know Standard
- Designing an auditing mechanism for uses/disclosures
- Implementing a mechanism to handle patient complaints
- Identifying all "Business Associates" and amending or creating written agreements with them
- Intranet, Internet, and Extranet implications
- Coordination with Washington State Uniform Health-care Information Act

Helpful Resources

For a comparison of state and HIPAA regulations, the following website is very helpful: www.healthprivacy.org (Select "State Law", then "View Our Full Report" and enter your "State Name").

Another excellent reference that was just published by the Office of Civil Rights in December can be found at www.hhs.gov/ocr/hipaa/privacy.html. The entire document can be viewed or it can be viewed in its entirety or by section. It is easy to read and has a Q&A format that is extremely helpful. Of special interest to laboratories right now is the section on Business Associate Agreements where it is clearly stated that a hospital or physician is not required to have a business associate agreement with the reference laboratory that is utilized. This seems to be the biggest lab issue at this time.

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Secretary, DOH: Mary Selecky
Health Officer: Maxine Hayes, MD, MPH
Director, PHL: Romesh Gautom, PhD
Program Manager, LQA: Gail Neuenschwander
Editor: Leonard Kargacin (206) 361-2804
Circulation: Leonard Kargacin (206) 361-2804

Comments, letters to the editor, information for publication, and requests for subscription can be directed to:
"ELABORATIONS"
Washington State Public Health Labs
1610 NE 150th Street
Shoreline, WA 98155

e-mail address: leonard.kargacin@doh.wa.gov

NOTE: Letters to the editor may be published unless specified otherwise by the author.

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Revision of CLIA Regulations - Effective April 24, 2003

by Gail Neuenschwander

The Centers for Medicare & Medicaid Services (CMS) published a final rule in the January 24, 2003 Federal Register addressing quality control and personnel requirements. The rule contains a restructuring of the Patient Test Management, Quality Control (QC) and Quality Assurance sections into two new subparts:

- J - Facility Administration for Nonwaived Testing
- K - Quality Systems for Nonwaived Testing

The final rule provides one set of QC standards that apply to both moderate and high complexity (nonwaived) testing. The restructuring follows the path of a patient specimen through the laboratory, i.e., specimen receiving, testing, and reporting of results. Quality control frequency is reduced in some specialties and subspecialties.

The rule finalizes the requirement for board certification of PhD directors for high complexity laboratories. This requirement becomes effective on February 24, 2003. Non-board certified directors who are currently serving as a director of a high complexity laboratory can continue to serve as director under a "grandfather" clause.

What does this mean for medical test sites (laboratories) in Washington? Medical test sites in Washington are regulated under the state Medical Test Site (MTS) Rules. The MTS rules directly reference the CLIA personnel requirements, so the requirement for board certification of PhD directors of high complexity laboratories will apply as of February 24, 2003. The Office of Laboratory Quality Assurance is in the process of reviewing the final CLIA rule to assess what changes will be needed in the MTS rules to remain in compliance with CLIA. When the assessment is completed, the necessary changes will be adopted through the state rule process.

For laboratories that are inspected/accredited by an approved accrediting organization, the requirements of the accrediting organization still apply.

The final CLIA regulations are available at: www.access.gpo.gov/nara/index.html (*Select Table of Contents for 2003; Select Friday, January 24, 2003; Scroll to Centers for Medicare & Medicaid Services/Rules/Standards and Certification*).

Clinical Laboratory Initiative Update

by Jon M. Counts, DrPH, MPH

Initiative Newsletter: In addition to the Initiative website (http://nwcphp.org/cli/), updates on the UW Clinical Laboratory Initiative will be provided through a periodic newsletter. The newsletter will also provide information on current and future research activities, assessment of research data, announcements of educational intervention strategies, references to articles concerning clinical microbiology, quality improvement in laboratory practice, and other articles of interest. If you wish to receive a copy of the electronic version of the newsletter, please send your email address to: jmc37@u.washington.edu.

Regional Technical Workshops: Your recommendations are needed to identify specific training that would be of value to you and your staff in antimicrobial susceptibility testing (AST). Regional workshops are planned for this Spring that will meet the needs of small and large hospitals, POLs, commercial laboratories, and the clinicians they serve. The following training needs were identified in the 2001 survey:

- Selection of antimicrobials for testing
- Enhancement of patient reports for interpretation of results
- Susceptibility testing for which there are no NCCLS standards
- Susceptibility testing for which NCCLS standards exist
- Assessment of technical competence in AST

Please provide any additional recommendations that you feel would enhance our quality improvement effort and provide assistance to you and your staff.

CD-ROM on Antimicrobial Susceptibility Testing: A CD-ROM on AST was developed by CDC to serve as an educational tool for laboratory professionals who provide this testing. It is designed to answer the following questions: How do antimicrobial agents work? What organisms should I test? What antimicrobial agents should I test? What methods should I use? and How should I report results? The CD-ROM will be distributed during the **Regional Technical Workshops** to be held this Spring. If you wish to receive a **free** copy of the CD prior to the workshops, please submit your request to ast@aphl.org or order online at www.aphl.org. AST updates can also be found on the MASTER website http://www.phppo.cdc.gov/DLS/master/default.asp.

Waived Testing Helpful Hints

In the last issue, we discussed Good Laboratory Practice (GLP) #4: Know the package insert. Here is GLP #5: Follow the procedure exactly.

√ Follow the test procedure step-by-step as indicated in the package insert.

√ Do not modify or change the test procedure, otherwise the test is no longer waived.

√ Do not mix reagents from different kits.

NOTE: Check this spot in future editions of Elaborations for more helpful hints with waived testing.

Calendar of Events

PHL Training Classes:

Blood Cell Morphology

March 12	Shoreline
March 13	Shoreline

Parasitology Part III: Trichromes

April 9-10	Shoreline

Advanced Heamtology

Aprl 30	Shoreline

WSSCLS/NWSSAMT Spring Meeting

April 24-26	Pasco

Northwest Medical Laboratory Symposium

October 22-25	Olympia

10th Annual Clinical Laboratory Conference

November 10	Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

ELABORATIONS
Washington State Department of Health
1610 NE 150th Street
Shoreline, WA 98155